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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,047	MEARES ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-27* is/are pending in the application.

4a) Of the above claim(s) *16-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-15 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Meares et al.

DETAILED ACTION

Election/Restrictions

The Election filed on March 24, 2005 in response to the Restriction Requirement of January 31, 2005 has been entered. Applicants have elected Group I, claims 1-15, as specifically drawn to a method of treating a subject with cancer by administration of a metal chelate and an antibody.

Applicant's election with traverse of Group I, claims 1-15 is acknowledged. The traversal is on the ground(s) that the restriction between Group I, directed to a method of treating cancer, and Group II, a method of obtaining an in vivo diagnostic image of a subject, would not impose a search burden on the Examiner. For example, while Applicants concede that the purposes of the methods recited in the claims differ between Group I and Group II, Applicants submit that both of the methods utilize the antibody of the invention and a metal chelate that is recognized by the antibody. These arguments have been carefully considered but are not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in the restriction requirement January 31, 2005.

In the instant case, the Examiner agrees with Applicants assertion that both methods, Groups I and II, utilize the antibody of the invention and metal chelate recognized by the antibody. However, the instantly claimed invention of Groups I and Group II are classified differently which would necessitate different searches of the US Patents. Moreover, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. For example, as stated in the prior restriction requirement and by Applicant "the purposes of the methods recited in the claims differ between Group I and Group II." Therefore, different searches and issues are involved in the examination of each group.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

The claims of Group III, claims 24-27, now amended to be either directly or indirectly dependent upon claim1, have been rejoined with Group I.

Claims 1-8 and 10-27 are currently pending.

Claims 16-23 have been withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-8, 10-15 and 24-27 are under consideration.

Note: After careful review, the Examiner has decided to withdraw the election of Z^1 and Z^2.

Information Disclosure Statement

The information disclosure statement filed 10/31/2003 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. The following reference appears to have been submitted to the Office for consideration but has not been cited on the IDS, WO 00/74729.

Specification

The specification/drawings (filed on 7/23/2003) are objected for improper disclosure of amino acid sequences and nucleotide sequences without a respective sequence identifier, i.e. a SEQ ID NOs:, see for example Figures 1-11. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

Claim Objections

Claim 8 is objected to because of the following informalities: Claim 8 is dependent from Claim 5, wherein the carbon marked "*" is of S configuration. However, Claim 5 is drawn to a chelate selected from substituted or unsubstituted DOTA and TETA. There does not appear to be the recitation of a carbon marked *. It appears that Claim 8 should depend from claim 6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, the two lines representing a "cleaved" bond extending from the two nitrogens renders the claim indefinite because it is unclear what functional groups are being excluded.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of antibodies comprising an antigen

recognition domain that recognizes a genus of macrocyclic metal chelate and a targeting moiety that binds specifically to a cancer cell. However, the written description in this case only sets forth an antibody referred to as 2D12.5 comprising an antigen recognition domain that recognizes a macrocyclic metal chelate represented in claim 6 and a targeting moiety that binds specifically to a cancer cell.

The specification teaches (page 5, lines 10-14) that specific antibodies of the invention include, but are not limited to, antibodies that recognize and bind to an array of macrocyclic metal chelate which are structurally distinct, wherein the "promiscuity" of the antibodies is a unique feature. With regards to the macrocyclic metal chelate, the specification teaches (page 4, lines 30-31) that metal chelates include not only metal chelates comprising all carbons, but also any metal chelate comprising four heteroatoms such as O, S, N and/or any combination thereof. With regards to the a N substituted macrocyclic metal chelate, the specification further (page 56, paragraph 0236 to 0237) that the metal chelate may include a substituted or unsubstituted ethyl bridge that covalently links at least two of the nitrogen atoms as represented in the formula shown on page 56 of the specification. However, the written description (specification, page 66 to 69) only reasonably conveys one species of antibody (2D12.5) comprising a recognition domain that recognizes a macrocyclic metal chelates represented on page 57 (claim 6); and therefore, is not commensurate with any and/or all antibodies comprising an antigen recognition domain that recognizes any and/or all macrocyclic metal chelates. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification

provides neither a representative number of antibodies that encompass the genus of antibodies that comprise a recognition domain which recognizes a macrocyclic metal chelate nor does it provide a description of structural features that are common to the antagonists. Further, the specification fails to provide a representative number of macrocyclic metal chelates that encompass the genus for which are recognized by an antibody along with a description of structural features that are common to the macrocyclic metal chelates. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of antibodies and metal chelates for which they recognize, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only forth an antibody referred to as 2D12.5 comprising an antigen recognition domain that recognizes a macrocyclic metal chelate represented in claim 6, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification and prior art, while being enabling for a method of treating cancer in a subject comprising administering an antibody comprising an antigen recognition domain that recognizes a macrocyclic metal chelate such as DOTA, wherein said antibody comprises a targeting moiety, anti-CEA, that binds to a cancer cell by binding with a cell surface antigen; and administering to said subject a metal chelate, does not reasonably provide enablement for a method of treating any cancer in a subject comprising administering an any and/or all antibodies comprising an antigen recognition domain that recognizes a macrocyclic metal chelate, wherein said antibody comprises any and/or all targeting moieties which binds to a cancer cell by binding to any and/or all cell surface receptors and cell surface antigens; and a macrocyclic metal chelate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The instant claims read a method of treating cancer in a subject comprising administering to said subject an antibody that comprises an antigen recognition domain that recognizes a macrocyclic metal chelate, wherein said antibody comprises a targeting moiety which binds to a cancer cell by binding to a cell surface receptors and cell surface antigens. Thus, the claims read on a method of treating any cancer in a subject comprising administering to the subject any and/or all antibodies

comprising an antigen recognition domain that recognizes a macrocyclic metal chelate, wherein said antibody comprises any and/or all targeting moieties which binds to a cancer cell by binding to any and/or all cell surface receptors and cell surface antigens; and administering a macrocyclic metal chelate.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn a method of treating any cancer in a subject comprising administering to the subject any and/or all antibodies comprising an antigen recognition domain that recognizes a macrocyclic metal chelate, wherein said antibody comprises any and/or all targeting moieties which binds to a cancer cell by binding to any and/or all cell surface receptors and cell surface antigens; and administering a macrocyclic metal chelate. The specification teaches (page 61, lines 1-9) that patients suffering from a disease or condition, such as cancer, can be treated via the steps of: (a) administering to the patient an antibody comprising; (i) an antigen recognition domain that specifically binds to the metal chelate and (ii) a targeting moiety that binds specifically to a cell by binding with a surface group; and (iii) a metal chelate, wherein the metal chelate and antibody bind to form an antibody-antigen pair. The specification further provides (Example 3, pages66-68) a monoclonal antibody, 2D12.5, which shows broad specificity and high affinity for all rare earth metal DOTA complexes. However, the specification appears to be silent on any working examples, wherein a macrocyclic metal chelate and an antibody comprising: (1) an antigen recognition domain that recognizes a macrocyclic metal chelate; (2) a targeting moiety which binds to a cancer cell are administered to a subject for the treatment of cancer. Specifically, the specification does not appear to suggest any variables such as the dose of either the antibody or metal chelate, the dose rate delivered, the tumor size, routes of administration, the times between administration, the radiosensitivity, or what the targeting moiety is.

Thus, the instant specification provides insufficient guidance and objective evidence to predictably enable one of skill in the art to use the invention as claimed. Although the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Those of skill in the art would recognize the

unpredictability of radioimmunotherapy. For example, Lovqvist *et al.* (J. Nucl. Med. 1998; 39: 1776-1777) discloses caveats and cautions in using pretargeting as a way of delivery radionucleotides selectively to tumors. These cautions include: (1) the immunogenicity of compounds such as streptavidin; (2) the presence of endogeneous biotin; (3) the rapid tumor clearance of monovalent chelates; (4) the restriction in using antibodies against chelates with limited nuclide applicability; and finally, (5) racemic mixtures of chelates may have a variable effect, wherein the enantiomeric nature influences targeting (page 1777, 1st column, 2nd paragraph). Lovquist *et al.* further teaches that while some progress has been made to address these points, the authors question whether this will be good enough quoting from Zhu et al (J. Nucl. Med. 1998; 39: 65-76) whom stated "pretargeting ... was neither sensitive enough for radioimmunodetection nor effective enough for radiotherapy" (page 1777, 1st column, 3rd-4th paragraph). Moreover, Goodwin *et al.* (Cancer 1997; 80: 2675-2680) discloses comparisons between the 3 step pretargeting method and the presently claimed 2 step pretargeting method (3 step outlined in Figure 1, page 2676). Goodwin *et al.* teach that pretargeting without the chase step, as in the presently claimed invention, requires a long waiting period for the blood MoAb concentration to fall, because even small amounts of MoAb remaining in the blood will immediately bind the effector molecules upon injection (page 2678, 1st column, 2nd paragraph to 2nd column). Thus, the teachings of Goodwin *et al.* stress the relationship between the time that the antibody is first administered and the second administration of the radionucleotide, i.e., the macrocyclic metal chelate. In addition to the time dependence discussed, *supra*, Goodwin *et al.* further disclose that many other question pertaining to pretargeting still remain unanswered such as optimal dosing schedule, molecular weight, valency, affinity constants, specific activity, rates of metabolism, and antigen modulation (Table 5, page 2679). More recently, Goldberg *et al.* (Cancer Immunol. Immunother. 2003; 52: 281-296) discloses the advancing role of radiolabeled antibodies in the therapy of cancer and the use of pretargeting strategies such as bispecific antibodies for the delivery of radionucleotides to enhance tumor to non-tumor ratios (abstract). In concurrence with Goodwin *et al.*, Goldberg *et al.* teach that the timing of the second injection of the radionucleotide is important, in order to achieve high tumor-to-background ratio when there is little to no bsAb circulating in the blood (page 285, 1st column, 1st paragraph). All of this underscores the criticality of providing workable examples which are not disclosed in the specification, particularly in an unpredictable art such as radioimmunotherapy.

Therefore, in view of the teachings above, and the lack of guidance and or exemplification in the specification, it would not be predictable that the method would function as contemplated. Thus, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-14 and 24-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Sharkey *et al.* (2002 ASCO Annual Meeting abstract, Orlando, Fl., May 18, 2002).

Sharkey et al disclose a method of treating a cancer in a subject comprising the steps of: (a) administering to said subject a bi-specific antibody or antibody fragment comprising one arm consisting of an antigen recognition domain that recognizes a targetable conjugate and a second arm which binds specifically to CEA (carcinoembryonic antigen); and (b) administering to said subject a targeting conjugate comprising a macrocyclic metal chelate, such as DOTA. With regards to the antibodies, the abstract teaches that the antibodies are prepared by chemical coupling the two "arm" regions together to form a chemical bond. With regards to the subject, the Sharkey et al. teach that the subjects were mice. Thus, while Sharkey *et al* does not teach a macrocyclic metal chelate comprising four nitrogen atoms, wherein at least two of the nitrogen atoms are covalently linked to a substituted or unsubstituted ethyl bridge or comprise a subunit shown in claim 4 or a formula of claim 6 or an S configuration DOTA, the referenced limitations are an inherent property of DOTA as evidenced by Sigma-Aldrich (see attached document). Thus, the claimed antibody appears to recognize the same macrocyclic metal chelate as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that a product of the prior art does not possess the same material, structural and functional characteristics of the claimed

product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1-8, 10-15 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (US 2002/0006379, 1/17/2002).

Hansen et al. teaches (Page 3, paragraphs 0031 to 0036 and page 10, paragraph 101-108) a method of treating a diseased tissue in a subject comprising the steps of: (a) administering to said subject a bi-specific antibody or antibody fragment comprising one arm consisting of an antigen recognition domain that recognizes a targetable conjugate and a second arm which binds specifically to a targeted tissue; and (b) administering to said subject a targeting conjugate comprising a macrocyclic metal chelate, such as DOTA or TETA. With regards to the antibodies, the publication teaches (page 14, paragraph 0135) that the antibodies are specific to a variety of cell surface or intracellular tumor-associated antigens and that the two variable regions are connected by a peptide linker (page 9, paragraph 0090). For example, Hansen et al. discloses (page 18, paragraph 0168) a targetable conjugate comprising a macrocyclic metal chelate, DOTA-Phe-Lys (HSG)-Tyr-Lys(HSG)-NH_2 which was synthesized to deliver therapeutic radioisotopes such as ^{90}Y or ^{177}Lu to tumors via bispecific tumor pretargeting, wherein the bispecific antibody is composed of one portion which binds to an antigen on the tumor and another portion which binds to an antigen recognition domain of the macrocyclic metal chelate. With regards to the subject, the publication teaches (page 9, paragraph 0091) that "subject" refers to any animal including, but not limited to, a human and other primates. Thus, while Hansen et al does not teach a macrocyclic metal chelate comprising four nitrogen atoms, wherein at least two of the nitrogen atoms are covalently linked to a substituted or unsubstituted ethyl bridge or comprise a subunit shown in claim 4 or a formula of claim 6 or an S configuration DOTA , the referenced limitations are an inherent property of DOTA as evidenced by Sigma-Aldrich (see attached document). Thus, the claimed antibody appears to recognize the same macrocyclic metal chelate as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that a product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the

absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 10-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-36 and 35-37 of copending Application Nos. 10/350,555 and 10/631,258 respectfully.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because a species anticipates a genus. In the instant case, the method of treating comprising administering a mutant antibody comprising an antigen recognition domain that recognizes a macrocyclic metal chelate claimed in the conflicting application, appears to fall within the same scope as the method of treating comprising administering a genus of antibodies comprising an antigen recognition domain that recognizes a macrocyclic metal chelate claimed in the application being examined and, therefore, a patent to a method of treating a subject comprising administering a genus of antibodies comprising an antigen recognition domain that recognizes a macrocyclic metal chelate, would necessarily extend the rights of a method of treating a subject comprising administering a mutant antibody comprising an antigen recognition domain that recognizes a macrocyclic metal chelate should the application being examined issue as a patent after the conflicting application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Therefore, NO claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Griffiths et al. (US 2003/0124057, filed 2001) discloses an anti-DOTA antibody and methods of using the antibody for the treatment of pathological diseases such as cancer (entire document).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
6/10/05